Institutional Review Board

North Dakota Department of Human Services

Off-Site Adverse Event Report

Type all answers

- **Any adverse events that occur during the study must be reported directly to the DHS Risk Manager (701-328-2311).**

1. General Information

Principal Investigator: _____ ☐ DHS ☐ Non-DHS

Address: _____

Dept./College: _____ Box No. _____ Tel./Fax #: _____

Co-Investigator(s): _____

_____

2. Protocol Information

Title of Project: _____

_____

_____

Sponsor/Grant agency: _____ Protocol/Clinical ID No. _____

3. Adverse Event Information

a. In the space below, please list all attached report numbers applicable to the report of the AE, i.e., MedWatch reports, Sponsor's Letter, etc. (*Tab down.)*

b. Does this AE significantly change the risk/benefit ratio? __Yes __No (Explain) (*Tab*)

c. Does this Adverse Event require change in the Informed Consent? __Yes __No
If yes, attach a copy of the revised consent form and highlight all revisions.

4. Principal Investigator Statement of Assurance

"I understand that I cannot initiate any changes in my approved protocol before I have received approval and/or complied with all contingencies made in connection with that approval."

_____ _____

Signature of Principal Investigator Date

Please return this application and any attachments to:

West Central Human Service Center
Attn: DHS IRB Chair
1237 West Divide Ave, STE. 5
Bismarck, ND 58501-1208

Proposal #_____